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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,587	07/29/2003	Kei Roger Aoki	17328CON5	1664

7590 05/10/2005

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EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 05/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/630,587	AOKI, KEI ROGER, ET AL	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 28-31 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 28-31 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 29 July 2003 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. In the preliminary amendment filed July 29, 2003, claims 1-27 have been cancelled, and new claims 28-31 have been added. Therefore, claims 28-31 are examined.

Applicant has requested declaration of interference against U.S. Patent application "US 2002/0192239" due to that both applications are directed to the same subject matter. The request is acknowledged and will be considered, when the application has allowable subject matter.

Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 28-31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U. S. Patent 6,869,610. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 28-31 in the instant application disclose a method for treating pain caused by neuralgia, or treating post-operative incisional wound pain, the method comprising administering a botulinum toxin to an afflicted area of a patient. This is obvious variation in view of claims 1-5 of the patent which disclose a method for alleviating neuralgia or treating pain that occurs after a surgical procedure, comprising peripheral administration of a therapeutically effective amount of

a botulinum toxin to a patient. Both sets of claims cite a method of treating neuralgia or post-operative pain, comprising peripheral administration of a botulinum toxin. Thus, claims 28-31 in present application and claims 1-5 in the patent are obvious variations of a method of treating neuralgia or post-operative pain, comprising peripheral administration of a botulinum toxin.

3. Claim 31 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 5 and 7-12 of U. S. Patent 6,464,986. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 31 in the instant application disclose a method for treating post-operative incisional wound pain, the method comprising administering a botulinum toxin to an afflicted area of a patient. This is obvious variation in view of claims 1, 3, 5 and 7-12 of the patent which disclose a method for treating post-operative pain, comprising peripheral administration of a therapeutically effective amount of a botulinum toxin to a patient. Both sets of claims cite a method of treating post-operative pain, comprising peripheral administration of a botulinum toxin. Thus, claim 31 in present application and claims 1, 3, 5 and 7-12 in the patent are obvious variations of a method of treating post-operative pain, comprising peripheral administration of a botulinum toxin.

4. Claims 28-31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 5, 9, 12, 13 and 28-32 of co-pending application 10/630,206. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 28-31 in the instant application disclose a method for treating pain caused by neuralgia, or treating post-operative incisional wound pain, the method comprising administering a botulinum toxin to an afflicted area of a patient. This is obvious variation in view of claims 1, 4, 5, 9, 12, 13 and 28-32 of the co-pending application

which disclose a method for treating pain, the method comprising administration such as peripheral administration of a botulinum toxin to a mammal. Both sets of claims cite a method of treating pain such as neuralgia or post-operative pain, comprising administration such as peripheral administration of a botulinum toxin. Thus, claims 28-31 in present application and claims 1, 4, 5, 9, 12, 13 and 28-32 in the co-pending application are obvious variations of a method of treating pain such as neuralgia or post-operative pain, comprising administration of a botulinum toxin.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 28-31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of co-pending application 11/003,677 (amendment filed December 3, 2004). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 28-31 in the instant application disclose a method for treating pain caused by neuralgia, or treating post-operative incisional wound pain, the method comprising administering a botulinum toxin to an afflicted area of a patient. This is obvious variation in view of claim 1 of the co-pending application which disclose a method for treating pain, comprising peripheral administration of a botulinum toxin to a mammal, wherein the pain is not associated with a muscle spasm. Both sets of claims cite a method of treating pain, comprising administration such as peripheral administration of a botulinum toxin. Thus, claims 28-31 in present application and claim 1 in the co-pending application are obvious variations of a method of treating pain such as neuralgia or post-operative pain, comprising administration of a botulinum toxin.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 28-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 28-31 are indefinite because the claims lack essential steps in the method for treating neuralgia or post-operative pain. The omitted steps are the effective amount of a botulinum ttoxin used and/or the outcome of the treatment. Claims 29 and 30 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

8. Claims 28-29 and 31 are indefinite because of the use of the term "botulinum toxin". The term "botulinum toxin" renders the claim indefinite, it is not clear which botulinum toxin or how many botulinum toxins are administered. Claim 29 is included in the rejection because it is dependent on a rejected claim and does not correct the deficiency of the claim from which it depends. Use of the term "a botulinum toxin" is suggested.

9. Claim 30 is indefinite because the claim is dependent from a cancelled claim, claim 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 28-30 are rejected under 35 U.S.C. 102(b) as anticipated by Binder (WO 95/30431).

Binder teaches a method of reducing a headache pain of neuralgia (Table 1(b), page 1, lines 13-29) by administering a therapeutically effective amount of a presynaptic neurotoxin such as botulinum toxin A in mammals including humans, where the neurotoxin can be administered at a localized site of pain (page 5, lines 25-30; Example I; claims 28-30).

Conclusion

11. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner

CHIH-MIN KAM
PATENT EXAMINER

CMK
May 7, 2005